IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SILVANA LANDAU, Plaintiff, v. D.O. CHRISTOPHER LUCASTI, et al., Defendants.	HONORABLE JEROME B. SIMANDLE Civil No. 06-1229 (JBS) **OPINION**

APPEARANCES:

Joseph A. Martin, Esq.
John Patrick Kahn, Esq.
Rebecca L. Rakoski, Esq.
ARCHER & GREINER, P.C.
One Centennial Square
P.O. Box 3000
Haddonfield, NJ 08033-0968
Attorneys for Plaintiff Silvana Landau

Carl D. Poplar, Esq.
David Poplar, Esq.
CARL D. POPLAR, P.A.
1010 Kings Highway South
Building Two
Cherry Hill, NJ 08034
Attorneys for Defendants Christopher Lucasti, Access One, Inc., and South Jersey Infectious Diseases, Inc.

SIMANDLE, District Judge:

This matter is before the Court on Plaintiff Silvana Landau's motion for partial summary judgment [Docket Item 66] and a motion for summary judgment filed by Defendants Christopher Lucasti, D.O., South Jersey Infectious Diseases, Inc. ("SJID"),

and Access One, Inc.[1] [Docket Item 65]. Plaintiff has brought a qui tam action[2] under the False Claims Act ("FCA"), 31 U.S.C. § 3729, in which the United States has declined to intervene. Plaintiff now seeks summary judgment on the question of liability, maintaining that there is no genuine dispute that Dr. Lucasti and his practice, SJID, knowingly presented false claims to the United States in which they sought payment from Medicare for services "incident to" Dr. Lucasti's outpatient intravenous antibiotic therapy treatment, when Dr. Lucasti was not actually present in his office during the infusions. Defendants also seek summary judgment, arguing that Plaintiff has not presented

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[1] Access One, Inc., is listed in the caption of this case, but is described in Plaintiff's complaint as "not named herein as a party." (Compl. ¶ 6.) At oral argument, Plaintiff's counsel agreed that they have no claims again Access One, and so the Court will grant summary judgment in favor of Access One.

[2]

> "Qui tam actions have a long history and were used in England before the foundation of this country." United States ex rel. Atkinson v. PA. Shipbuilding Co., 473 F.3d 506, 509 (3d Cir. 2007). The term "qui tam" itself is a shortening of "the Latin phrase qui tam pro domino rege quam pro se ipso in hac parte sequitur, which means 'who pursues this action on our Lord the King's behalf as well as his own.'" Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 769 n. 1 [] (2000). Under modern practice, qui tam actions are brought by private plaintiffs on behalf of the Government in exchange for some portion of any resulting damages award. See id. at 773-74 [].

Rodriguez v. Our Lady of Lourdes Med. Center, 552 F.3d 297, 299 n.1 (3d Cir. 2008).

sufficient evidence that the subject claims were false or that Dr. Lucasti had the scienter necessary for liability under the FCA. For the reasons discussed below, the Court will deny Defendants' motion in part, and grant Defendants' motion in part, as it relates to Medicare claims submitted prior to January 1, 2002 and the claims against Access One. The Court will further deny Plaintiff's motion for partial summary judgment as to liability, but grant partial summary judgment in favor of Plaintiff as to the unambiguous meaning and applicability of the post-January 1, 2002 Medicare regulations outlining the requirements for services "incident to" the services of a physician.

I. BACKGROUND

A. Relevant Medicare Regulations

The federal Medicare program, administered by the Centers for Medicare and Medicaid Services ("CMS"),[3] provides health care to elderly and disabled Americans by offering insurance for hospital services (Medicare Part A) and supplemental benefits for physician and outpatient services (Medicare Part B). 42 U.S.C. §§ 1395-1395ii. Part B covers "medical and other health services," 42 U.S.C. § 1395k(a), which includes "services and supplies (including drugs and biologicals which are not usually

[3] CMS was formerly known as the Health Care Financing Administration ("HCFA"). 42 C.F.R. § 400.200.

self-administered by the patient) furnished as an incident to a physician's professional service," 42 U.S.C. § 1395x(s)(2). Agency regulation governs whether a service is "incident to" a physician's service. 42 C.F.R. § 410.26.

The current regulations (effective January 1, 2002) governing payment for a physician's medical services read, in relevant part:

> (b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).
> . . .
> (5) Services and supplies must be furnished under the direct supervision of the physician (or other practitioner). The physician (or other practitioner [4]) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

42 C.F.R. § 410.26(b)(5). "Direct supervision" is defined as "the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii)." 42 C.F.R. § 410.26(a)(2). Section 410.32(b)(3)(ii) states:

> Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is

[4] "Practitioner means a non-physician practitioner who is authorized by the Act to receive payment for services incident to his or her own services." 42 C.F.R. § 410.26(a)(6).

> performed.

42 C.F.R. § 410.32(b)(3)(ii).

Prior to January 1, 2002, however, 42 C.F.R. § 410.26 stated only this:

> Medicare Part B pays for services and supplies incident to a physician's professional services, including drugs and biologicals that cannot be self-administered, if the services or supplies are of the type that are commonly furnished in a physician's office or clinic, and are commonly furnished either without charge, or included in the physician's bill.

42 C.F.R. § 410.26(a)(2001).

In addition, there are separate provisions, in effect for the entire relevant period, governing payment for services incident to the services of a physician's assistant or nurse practitioner:

> A physician assistant's, nurse practitioner's, and clinical nurse specialists' services, and services and supplies furnished incident to their professional services, are paid in accordance with the physician fee schedule. The payment for a physician assistants' services may not exceed the limits at § 414.52 of this chapter. The payment for a nurse practitioners' and clinical nurse specialists' services may not exceed the limits at § 414.56 of this chapter.

42 C.F.R. § 405.520(a). Both Section 414.52 and Section 414.56 limit payment for such physician's assistant or nurse practitioner services to no more (and sometimes less) than 85 percent of the physician fee schedule amount. 42 C.F.R. §§ 414.52, 414.56.

B. Facts

Plaintiff Silvana Landau worked as the office manager at SJID from August 1998 through the Summer of 2005. (Landau Dep. at 19, 31.) Dr. Lucasti is a doctor of osteopathy who specializes in the treatment of infectious disease, including outpatient intravenous antibiotic treatment (or infusion treatment). (Lucasti Dep. at 9.) Included among his patients were those covered by Medicare. (Id. at 26-32.) In order to seek reimbursement from Medicare for infusion treatments made to Medicare patients, Dr. Lucasti and his practice were required to submit Health Insurance Claim Form CMS-1500 to CMS. (CMS-1500, Pl. Exh. B.) That form includes the following language:

> I hereby certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations.

(Id.) Defendants also included the medical provider's identification number and a code describing the treatment given in each Medicare claim. (Morey Dep. at 67; Health Law Network Report, Pl. Exh. I.) SJID billed the vast majority of infusion therapy claims to Medicare under Dr. Lucasti's provider number. (Morey Dep. at 67; Health Law Network Report, Pl. Exh. I at 7.)

SJID performed infusion therapy seven days a week, from 9 a.m. to 5 p.m during the week and 9 a.m. to noon on the weekends. (Mayer Dep. at 15-16; DeSantis Dep. at 37.) Registered nurses

hired by SJID generally provided the infusion treatments. (DeSantis Dep. at 18-19.) Dr. Lucasti testified during his depositions that he was not always in his office when Medicare patients were receiving infusion therapy, though he was available at all times on his cellular phone, and that he did bill Medicare for treatment given as incident to his professional service even when he was not present during the period between 2000 and 2006. (Lucasti Dep. at 29, 46.) Dr. Deborah Bayer, whom SJID employed from August 1999 until May 2003, similarly testified that SJID nurses provided infusion therapy without a doctor in the office. (Bayer Dep. at 21.) Dr. Lucasti testified that he believed the Medicare regulations only required him to be "[s]imply available, either in the office suite or via telephone or where I'm available to my nurses." (Lucasti Dep. at 27.) He was apparently open about this practice, for according to Plaintiff's testimony Dr. Lucasti described his practice to another doctor interested in starting an infusion practice during a dinner in 2004. (Landau Dep. at 70-73.)

According to Plaintiff, in the fall of 2001, she and Deborah Morey, who has been responsible for billing at SJID since 2000, attended an infectious disease seminar in Nashville, Tennessee. (Landau Dep. at 50-51; Morey Dep. at 15, 142.) During this seminar Plaintiff and Ms. Morey developed concerns that SJID's practice for providing infusion therapy under treatment code 90780 was in conflict with Medicare regulations and requirements

-- specifically, Ms. Morey was concerned that Dr. Lucasti was not providing "direct supervision" as required by the regulations. (Landau Dep. at 53; Morey Dep. at 120.) Both Plantiff and Ms. Morey understood "direct supervision" to require the doctor to be physically on the premises during the infusion. (Landau Dep. at 54; Morey Dep. at 121-22.) After returning from the seminar Plaintiff and Ms. Morey met with Dr. Lucasti in his office, and Ms. Morey brought with her a copy of the 90780 billing code and a Medicare document giving the definition of "direct supervision." (Landau Dep. at 53-54.) Plaintiff and Ms. Morey expressed their concerns regarding "direct supervision" and its requirement that the doctor be physically present, and Dr. Lucasti responded that he believed he was providing "direct supervision," which only required him to be immediately available. (Landau Dep. at 54-55; Morey Dep. at 121-22.) Plaintiff again warned Dr. Lucasti about his practice sometime in 2004. (Landau Dep. at 57.)

Meanwhile, the current regulations defining "direct supervision" took effect January 1, 2002. Sometime in January 2002, Barbara Nolet, President of NW Management Associates, prepared recommendations for SJID's preparation for the Joint Commission on the Accreditation of Health Care Organizations ("JCAHO") accreditation survey. (Nolet Report, Pl. Exh. G.) Included in the report was a manual entitled "Outpatient Parenteral Antimicrobial Therapy In Physician Office Based Infusion Center," which at page six under the heading "Medicare

Fraud and Abuse" stated:

> A specific area of concern in terms of OPAT might be the benefit which reimburses the physician for in-office infusion. The infusion is covered specifically when it is incident to the physician office visit, and should be provided directly by the physician or under the direct supervision of the physician. Any variation on this which is still billed through the physician provider number could be considered fraud.

(Id.)

Despite the concerns of Plaintiff and Ms. Morey, and the plain language of the current regulation (to be discussed below), Defendants present evidence that industry practice does not involve having a doctor on the premises during infusion treatment for Medicare patients. Defendants offer the expert report of Dr. Alan Tice, a specialist in infectious diseases with more than thirty years of experience with infusion therapy, during which time he has researched the subject and written extensively on the topic. (Tice Report, Pl. Exh. H at 1-2.) Dr. Tice repeatedly states that "The standard practice in the medical industry does not require a physician to always be present in the office suite at all time during OPAT [infusion treatment], as long as he is available by telephone and there are medical professionals in the office monitoring the OPAT." (Id. at 4, 10.) Dr. Philip Paparone confirms that Dr. Lucasti's infusion practice meets "the standard of practice executed by multiple practitioners who engage in outpatient antibiotic therapy services to Medicare patients" in southern New Jersey. (Paperone Report, Def. Exh.

17.)

Dr. Tice's opinion regarding the regulatory requirements is more ambiguous. He says:

> The "industry standard" for OPAT therapy of Medicare patients does not require a physician to be present in the office suite at all times during OPAT. With the availability of trained, experienced nurses, there is no requirement that a doctor be present for any private insurance company I know. The only payer I know with restrictions such as these is Medicare.

(Id. at 10) (emphasis added). But he later states:

> I do not know of past or present circumstances where the HCFA or the federal government has interpreted and/or enforced the Medicare regulation against Infectious Disease physicians in the way that is being asserted by the Plaintiff in this case.

(Id. at 11.) During his deposition, Dr. Tice repeatedly characterizes Plaintiff's view of the Medicare regulations as one "interpretation" of the Medicare requirements, and further states, incorrectly, that there is no regulation that specifically requires a doctor to be physically present in the office suite at all times during infusion therapy. (Id. at 55, 57-58, 137.) However, when read the current language of 42 C.F.R. § 410.32, Dr. Tice acknowledge that his view of the industry standard is inconsistent with the express language of the regulation. (Id. at 49-52.)

C. Procedural History

On March 15, 2006, Plaintiff filed the instant action under seal seeking relief under the FCA. On August 30, 2006, the

United States informed the Court that it would decline to intervene and the Court lifted the seal. After three years of contentious discovery practice, on October 16, 2009, both parties submitted their motions for summary judgment, and the Court heard extensive oral argument on December 18, 2009.

II. DISCUSSION

A. Standard of Review

Summary judgment is appropriate when the materials of record "show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In deciding whether there is a disputed issue of material fact, the court must view the evidence in favor of the non-moving party by extending any reasonable favorable inference to that party; in other words, "the nonmoving party's evidence 'is to be believed, and all justifiable inferences are to be drawn in [that party's] favor.'" Hunt v. Cromartie, 526 U.S. 541, 552 (1999) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986)). The threshold inquiry is whether there are "any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Liberty Lobby, 477 U.S. at 250; Brewer v. Quaker State Oil Refining Corp., 72 F.3d 326, 329-30 (3d Cir. 1995) (citation omitted).

Although entitled to the benefit of all justifiable

inferences from the evidence, "the nonmoving party may not, in the face of a showing of a lack of a genuine issue, withstand summary judgment by resting on mere allegations or denials in the pleadings; rather, that party must set forth 'specific facts showing that there is a genuine issue for trial,' else summary judgment, 'if appropriate,' will be entered." United States v. Premises Known as 717 South Woodward Street, Allentown, Pa., 2 F.3d 529, 533 (3d Cir. 1993) (quoting Fed. R. Civ. P. 56(e)) (citations omitted).

B. False Claims Act

"To establish a prima facie case under the FCA, the relator must prove: '(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.'" U.S. ex rel. Hefner v. Hackensack University Medical Center, 495 F.3d 103, 109 (3d Cir. 2007) (quoting Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 182 (3d Cir. 2001)). For the purposes of the FCA, "knowing" can mean either "actual knowledge of the information," "deliberate ignorance of the truth or falsity of the information," or "reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). Though liability under the False Claims Act does not require a specific intent to defraud, 31 U.S.C. § 3729(b)(1)(B), Congress did not intend to punish "honest mistakes or incorrect claims submitted through

mere negligence." Hefner, 495 F.3d at 109 (internal citations omitted).

1. Defendants' Motion for Summary Judgment

Defendants attack two separate, but interrelated, prongs of Plaintiff's prima facie case under the FCA. They argue that Plaintiff's interpretation of the Medicare regulations to require the doctor's physical presence in the office suite during infusion treatment in order to bill Medicare for Dr. Lucasti's infusion services is incorrect, and therefore there were no false claims for payment. Even if Plaintiff is correct that Dr. Lucasti's physical presence was required to submit claims to Medicare under his provider number, Defendants argue that Plaintiff has not presented evidence from which a reasonable fact-finder could find that Dr. Lucasti "knowingly" (that is, with direct knowledge, deliberate indifference, or reckless disregard for the truth) submitted these false claims. For the reasons outlined below, that the Court finds that Medicare regulations post-January 1, 2002 unambiguously require the doctor to be physically present in the office suite while services are rendered, but the pre-January 1, 2002 regulations are ambiguous. The Court further finds that there is sufficient evidence from which a fact-finder could find that after January 1, 2002, Dr. Lucasti was at least reckless with regard to the truth of the Medicare claims at issue here.

(a) Claims Submitted After January 1, 2002

"Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed." United States v. R&F Properties of Lake County, Inc., 433 F.3d 1349, 1356 (11th Cir. 2005) (citing United States v. Calhoon, 97 F.3d 518, 524 (11th Cir. 1996) and Peterson v. Weinberger, 508 F.2d 45, 52 (5th Cir. 1975)). Since January 1, 2002, the Medicare regulations have stated that Medicare will pay for services "incident to the services of a physician" so long as the services are provided under the "direct supervision" of the physician. 42 C.F.R. § 410.26(b)(5) (2002). Similarly, since January 1, 2002, "direct supervision" has required that the physician "be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure." 42 C.F.R. § 410.26(a)(2) (2002), 410.32(b)(3)(ii) (2002). "This regulatory language unambiguously requires that a physician be present in the office." R&F Properties, 433 F.3d at 1356; U.S. ex rel. Lockyer v. Hawaii Pacific Health, 490 F. Supp. 2d 1062, 1075 (D. Haw. 2007) ("The rules simply require the supervising physician to be present in the office suite and immediately available to furnish assistance.")

Defendants attack the plain meaning of these regulations on several fronts, none of which is availing. Defendants maintain that Plaintiff's "interpretation" of the regulations is strained

because it requires "cross-referencing different parts of various sources." Defendants do not dispute, nor could they, that they billed for infusion treatments as a service "incident to" Dr. Lucasti's treatment and therefore 42 C.F.R. § 410.26 must be applied. And it is Section 410.26 that cross-references the definition of "direct supervision" in § 410.32(b)(3)(ii), not Plaintiff. Defendants fault the regulations for not specifically referencing infusion therapy, but the general applicability of § 410.26 is plain from its face (it is entitled "Services and supplies incident to a physician's professional service: Conditions"), and from its related statutes, 42 U.S.C. §§ 1395k(a), 1395x(s), which govern the scope of Medicare payments under Part B.

Finally, Defendants emphasize the language in the current regulation that permits Medicare payment for service incident to the care of a "practitioner" and allows the practitioner to provide the necessary direct supervision. 42 C.F.R. § 410.26(b)(5). Defendants point out, and Plaintiff agrees, that all of SJID's infusion treatments were supervised by experienced, registered nurses. The flaw in Defendants' argument, however, is that Defendants did not bill Medicare for the infusion services "incident to" the services of the SJID nurses, but instead the vast majority of claims identified Dr. Lucasti himself as the provider, using the billing code for physician services. Assuming that any of the nurses who provided the infusion

treatments could be "practitioners" as defined in the regulations,[5] it is clear that they functioned as auxiliary personnel in Dr. Lucasti's practice. As CMS explained:

> When a claim is submitted to Medicare under the billing number of a physician (or other practitioner) for an incident to service, the physician is stating that he or she either performed the service or directly supervised the auxiliary personnel performing the service. Accordingly, the Medicare billing number of the ordering physician (or other practitioner) should not be used if that person did not directly supervise the auxiliary personnel.

66 Fed. Reg. 55246-01, 55267 (November 1, 2001).

The need to properly identify the provider of services is not insignificant because nurse practitioners, clinical nurse specialists, and physician assistants all receive no more than 85 percent of the physician fee schedule amount for the service. 42 C.F.R. §§ 405.520(a), 414.52, 414.56. Thus, the Seventh Circuit very recently observed:

> [T]he general rule under these programs is that physician's assistants must bill Medicare and Medicaid at a lower rate for the work they do than if the same work had been performed by a doctor. However, a health-care provider may use a doctor's identification number to bill Medicare and Medicaid for services performed by a physician's assistant -- and thus obtain reimbursement at the doctor's rate -- if the assistant rendered services "incident to" the services of a physician. Most relevant for purposes of this case, an assistant's services are "incident to" a physician's services

[5] Neither party discusses whether these nurses were "authorized by the Act to receive payment for services incident to his or her own services" as required for a "practitioner." 42 C.F.R. 410.26(a)(6).

> only if the doctor directly supervises the assistant's performance.

Glaser v. Wound Care Consultants, Inc., 570 F.3d 907, 911 (7th Cir. 2009); R&F Properties, 433 F.3d at 1352-53.[6] Services rendered "incident to" the services of a nurse practitioner or physician's assistant (as the "other practitioner") need not be directly supervised by the doctor, but cannot consequently be billed at the doctor's full rate. R&F Properties, 433 F.3d at

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[6] The Eleventh Circuit, under nearly identical circumstances, made the same observation:

> Healthcare providers may bill Medicare Part B for the services of physician assistants and nurse practitioners in one of two ways; the amount of reimbursement the providers receive is dependent on the billing method. Physician assistant or nurse practitioner services may be billed as services "incident to the service of a physician." 42 CFR §§ 410.10, 410.26. To be correctly billed in this manner, the physician assistant or nurse practitioner services must have been provided under certain circumstances. When physician assistant or nurse practitioner services are billed as "incident to the service of a physician," the physician's Unique Provider Identification Number (UPIN) is used on the bill submitted to the FI [fiscal intermediary]. Alternatively, a provider may bill Medicare for physician assistant and nurse practitioner services under the physician assistant's or nurse practitioner's own UPIN. Billing Medicare in this second way indicates that the physician assistant or nurse practitioner has performed the service under some level of supervision by a physician, but the requirements of 42 CFR § 410.26 have not necessarily been met. For services billed under a physician assistant's or nurse practitioner's UPIN, the FI pays 85% of what it would pay for the same services billed under a physician's UPIN.

R&F Properties, 433 F.3d at 1352-53.

1352-53. Under the post-January 1, 2002 regulations is it clear that, so long as Defendants wished to receive the full amount of the physician fee schedule based on Dr. Lucasti's services, Dr. Lucasti was required to directly supervise the infusion treatment by remaining in the office suite during such treatment.[7]

The above analysis does not resolve the question for the parties, however, because Plaintiff must also submit evidence from which a fact-finder could find that Dr. Lucasti knew the claims to Medicare based on infusion treatments for which he was not physically present were false, or that he was deliberately indifferent or reckless as to this alleged fact. The Court finds that there is evidence that as of January 1, 2002 Dr. Lucasti was at least reckless as to the truth of his claims for Medicare reimbursement. Plaintiff has offered evidence that she and Debra Morey, who did the billing for SJID, warned Dr. Lucasti that his billing practices might violate Medicare regulations and policy,

[7] During oral argument, defense counsel maintained that the Court's opinion, should it favor Plaintiff's position, would have a disastrous effect on outpatient infusion therapy practice and consequently, defense counsel argued, on the patients themselves. The Court does not find such significance (or such dire results) in its opinion. By noting the plain and generally applicable language in the Medicare regulations, the Court is merely following in the steps of every other court to consider this question. Moreover, Dr. Lucasti and other providers of outpatient infusion therapy may continue to provide services through nurse practitioners and physician assistants, altering only their method of billing Medicare to accurately reflect who is truly providing the service -- or they may directly supervise their own practice as required by the plain language of the Medicare regulations in order to bill incident to their own services.

and that the women brought forth documents to Dr. Lucasti to support their concerns. The January 1, 2002 amendments made the women's concerns concrete, and not a subject of mere interpretation. A reasonable jury could find that Dr. Lucasti's failure to consider the relevant governing regulations was reckless. As Plaintiff correctly points out, Defendants were obligated to familiarize themselves with the Medicare legal requirements. See Heckler v. Community Health Services of Crawford County, Inc., 467 U.S. 51, 63 (1984) ("Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law[.]").

Defendants rely on the Third Circuit's opinion in Hefner for their position that Plaintiff has submitted insufficient evidence of scienter to survive summary judgment. Hefner can be distinguished from the instant case. In Hefner, the evidence showed the defendant hospital knew that it could not request federal grant funding for services that were also billed to Medicare, but that due to a "breakdown" in the hospital's billing system, such double-billing had occurred. 495 F.3d at 106-07. As soon as the hospital was notified of this problem, however, the hospital took corrective measures and ultimately returned the improper payments to Medicare. Id. at 107. The Third Circuit found that the plaintiff had presented no evidence that the hospital knew it was double-billing or that it had any reason to believe there were problems with its billing system, and

consequently affirmed the grant of summary judgment in favor of defendants. Id. at 109-10.

By contrast here, there is evidence from which a reasonable fact-finder could find that Defendants knew about their allegedly false billing practice (Dr. Lucasti and his staff testified that Medicare was billed for infusions that were performed when no doctor was present in the office suite) and that Dr. Lucasti was warned about this falsity by Ms. Landau, Ms. Morey, and Ms. Nolet and failed to change it even after the regulations were amended to clarify the meaning of direct supervision, suggesting that he was at least reckless as to the law governing his Medicare claims (even assuming Dr. Lucasti genuinely believed that he was not violating any Medicare regulations).[8] Summary judgment for Defendants is not appropriate for these post-January 1, 2002 claims.

(b) Claims Submitted Prior to January 1, 2002

Plaintiff's claims arising out of Defendant's billing practice prior to January 1, 2002, however, cannot survive because Plaintiff has not submitted evidence from which a reasonable fact-finder could find that Defendants knowingly submitted false claims. The regulations pre-January 1, 2002 are

[8] Defendants also rely on U.S. ex rel. K & R Ltd. Partnership v. Massachusetts Housing Finance Agency, 456 F. Supp. 2d 46 (D.D.C. 2006), which can be distinguished, among other reasons, because the district court found that the defendants had properly interpreted the relevant rules and regulations governing their claims and so the claims were not false.

far from clear. As already noted, they read only:

> Medicare Part B pays for services and supplies incident to a physician's professional services, including drugs and biologicals that cannot be self-administered, if the services or supplies are of the type that are commonly furnished in a physician's office or clinic, and are commonly furnished either without charge, or included in the physician's bill.

42 C.F.R. § 410.26(a). This language, even read in conjunction with the language of the Form HCFA/CMS 1500 (which requires "immediate personal supervision") is ambiguous as it relates to the requirement that the doctor be physically present in the office. R&F Properties, 433 F.3d at 1356 ("We agree that the regulatory language in effect until January 1, 2002 was ambiguous."). The regulation furnished on the type of service provided, rather than upon who is providing it, in the physician's office, and the regulation uses the passive voice ("are commonly furnished") twice in describing these services, without speaking to the physician's requirement to be present in the office. This ambiguity is fatal to Plaintiff's quest for damages related to Defendants' pre-January 1, 2002 Medicare claims.

Plaintiff spends very little time on the pre-January 1, 2002 regulation, though her claims span from 2000 to 2006. In fact, her only reference to this issue is in her opening brief, at page 13, where she acknowledges that Section 410.26 was amended on January 1, 2002 to include the explicit requirement of physical

presence. She does, however, drop a footnote, in which she incorporates the interpretation of "incident to" from section 2050.1 of the Medicare Carrier's Manual ("MCM") prior to January 1, 2002, which did require physical presence of the provider. See R&F Properties, 433 F.3d at 1358 n.3 (citing Medicare Carriers Manual Part 3, Claims Process Pub. 14-3 (MCM), § 2050, at 2-19). Plaintiff then cites to several cases involving Medicare payment disputes that incorporate the MCM's interpretation of "incident to." See Gary Gibbon, M.D., Inc. v. Thompson, 121 F. App'x 703 (9th Cir. 2005); Downtown Medical Center/Comprehensive Health Care Clinic v. Bowen, 944 F.2d 756 (10th Cir. 1991); Dumke v. Sec'y of Health and Human Servs., No. 05-0268, 2006 WL 2731071 (D. Ariz. Sept. 25, 2006). These cases do not aid Plaintiff on the issues presented, however, for the question is not whether Medicare was required to reimburse Dr. Lucasti for his services, but whether Plaintiff knowingly submitted false claims.

There is no evidence from which a reasonable jury could find that Dr. Lucasti knew, or was reckless or deliberately indifferent to the fact, that he was submitting false claims prior to January 1, 2002. Neither the governing regulations nor Form HCFA/CMS 1500 make any mention of the requirement of physical presence. Plaintiff has proffered no evidence that Defendants actually had, or had access to, the MCM Manual. No reasonable fact-finder could find that a prudent doctor, faced

with a regulation and a form which do not require the physician's physical presence and an industry-wide practice that did not require such physical presence, should have looked beyond the governing regulations based only on the concerns of two of his staff members. At most, such facts might support a jury's finding Dr. Lucasti to have been negligent, but his conduct prior to January 1, 2002, even viewing the facts in the light most favorable to Plaintiff, does not meet the scienter element of the False Claims Act. Claims arising from billings for infusion therapy services rendered prior to January 1, 2002, will be dismissed.

2. Plaintiff's Motion for Partial Summary Judgment on Liability

Plaintiff seeks summary judgment on Defendants' liability under the FCA, arguing that this is no genuine dispute that Defendants presented claims for payment to the United States, that at least some of those claims for payment were false, and that Defendants knew the claims were false. The Court finds, for the reasons expressed below, that while the post-January 1, 2002 Medicare regulations are unambiguous and require the physical presence of the physician to bill incident to his services, summary judgment for Plaintiff is not appropriate on the scienter prong of the FCA.

Summary judgment is not appropriate on the issue of Dr. Lucasti's scienter as it relates to his Medicare claims. The

Court "must heed the basic rule that a defendant's state of mind typically should not be decided on summary judgment." U.S. Ex. Rel. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 411 (3d Cir. 1999). Defendants have submitted the expert testimony of Dr. Tice, who both challenged the plain-meaning interpretation of the current regulations and stated that the standard practice in the infusion therapy field was not to abide by the plain meaning of Section 410.26, but instead considered it sufficient for the doctor to be immediately available. A fact-finder could find that Plaintiff's warnings, and even Section 410.26 (which does not, as Defendants point out, expressly reference infusion treatment or include the detailed definition of "direct supervision," instead referring to Section 410.32, which also makes no reference to infusion treatment), were not obvious warning signs in the face of an apparently industry-wide contrary practice. See Crane Helicopter Ser., Inc. v. U.S., 45 Fed. Cl. 410, 434 (1999) ("[T]he [FCA] covers . . . those who ignore obvious warning signs.") (citing S. Rep. No. 99-345, at 21 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5286)[9]. A jury

[9] The Senate Report for the False Claims Amendment Act of 1986 states:

> In both bills, the constructive knowledge definition attempts to reach what has become known as the 'ostrich' type situation where an individual has 'buried his head in the sand' and failed to make simple inquiries which would alert him that false claims are being submitted. While the Committee intends that at least some inquiry be

could find that a reasonable and prudent doctor would be satisfied by the experts in his own field and was merely negligent in not taking further steps to learn that the plain language of the regulations did apply to his practice. Consequently, while there is evidence to support a finding that Dr. Lucasti and SJID were reckless in their billing practices, there is also evidence which supports a finding that they were merely negligent. This genuine dispute regarding a material element of Plaintiff's claim forbids summary judgment on the issue of liability.

3. Plaintiff's Motion for Partial Summary Judgment on the Meaning and Applicability of the Medicare Regulations

While material facts are in dispute regarding Dr. Lucasti's state of mind after January 1, 2002, precluding summary judgment for Plaintiff as to liability, the Plaintiff has prevailed on one important part of her summary judgment motion, namely, the legal interpretation of the post-January 1, 2002 Medicare Part B requirement for "services incident to the services of a physician" to be reimbursed by Medicare. The Court finds that Plaintiff has established that the duly promulgated Medicare regulations unambiguously required, since January 1, 2002, that

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> made, the inquiry need only be 'reasonable and prudent under the circumstances', which clearly recognizes a limited duty to inquire as opposed to a burdensome obligation.

S. Rep. No. 99-345, at 21 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5286).

services billed as incident to the service of a physician -- including outpatient infusion therapy -- must be provided under the physician's direct supervision, meaning that the physician must be both "present in the office suite" and "immediately available" to furnish direction and assistance throughout the procedure. 42 C.F.R. §§ 410.26(b)(5), 410.32(b)(3)(ii), supra.

Even if one assumes for purposes of this motion that the industry-wide practice for infusion therapy does not require the physician to be present in the office throughout the administration of the infusion treatment so long as the physician is available by telephone and competent medical professionals are present, such standard of care is not relevant to defining the unambiguous regulations requiring the physician's availability and presence in the office suite when billed as incident to physician services. The present dispute is not about whether Defendants' methods compromised patient care, nor about whether infusion therapy was actually rendered, but instead whether Dr. Lucasti's practice of not being physically present in his office when infusion treatment was given entitled his office to bill Medicare for services as "incident to the services of a physician."

The answer lies in Medicare's own regulations for reimbursement of physician-rendered services. Quite plainly, Medicare requires the physician's personal supervision, including physical presence, to bill at the physician services rate;

otherwise, assuming the assistants or nurses administering the infusion therapy are qualified non-physician practitioners, the Medicare reimbursement can be sought only at the lower rate for such practitioners. To the extent a physician is not present as required, yet bills Medicare for a service incident to the services of a physician, that claim violates the Medicare requirement and is false. Partial summary judgment, pursuant to Rule 56(d), Fed. R. Civ. P.,[10] will be granted in Plaintiff's favor declaring that there is no genuine dispute as to the meaning and interpretation of 42 C.F.R. §§ 410.26(a)(2), 410.26(b)(5), and 410.32(b)(3)(ii), as applied to providing infusion therapy incident to a physician's professional services

[10] Under Rule 56(d)(1), the Court should "issue an order specifying what facts -- including items of damages or other relief -- are not genuinely at issue. The facts so specified must be treated as established in the action." The interpretation of a statute or regulation is a matter of law; a jury would determine a statute's meaning only if a statutory ambiguity colored its application to the circumstances of the case. No such ambiguity is presented here. Thus, the Court is able to resolve, as a matter of law, that any claims submitted by Dr. Lucasti to Medicare on or after January 1, 2002 as incident to his own professional services, when he was not physically present for the provision of those services, are false and satisfy the second prong of Plaintiff's prima facie case under the FCA. See Rosefielde v. Falcon Jet Corp., 701 F. Supp. 1053, 1061 (D.N.J. 1988) (granting partial summary judgment as to conspiracy element of price fixing claims, but denying plaintiff complete summary judgment where material facts remained in dispute as to other elements); Koutsoubos v. Boeing Vertol, Div. of Boeing Co., 553 F. Supp. 340 (E.D.Pa. 1982) (granting partial summary judgment as to two elements of the government contract defense, but declining to grant plenary summary judgment), affirmed, 755 F.2d 352 (3d Cir. 1985), abrogated on other grounds by Maguire v. Hughes Aircraft Corp., 912 F.2d 67, 69-70 (3d Cir. 1990).

on and after January 1, 2002, and that claims submitted for infusion therapy incident to a physician's services where no physician was present in the office suite during administration of the infusion are false.

III. CONCLUSION

For the foregoing reasons, the Court will deny Defendants' motion for summary judgment except as to any claims made before January 1, 2002 and the claims against Access One. The Court will deny Plaintiff's motion for partial summary judgment on the issue of liability, but will grant summary judgment as to the unambiguous meaning and general applicability of the post-January 1, 2002 Medicare regulations. It remains for Plaintiff to prove at trial that Defendants caused such claims for infusion therapy incident to physician's services to be submitted to Medicare after January 1, 2002, and that Defendants knew these claims were false or fraudulent, meaning either actual knowledge of falseness, deliberate ignorance of the truth or falsity of the claim, or reckless disregard of the truth or falsity of the claim, and to prove for each such claim the amount of damages sustained by Medicare.[11]

[11] The issue of quantum of damages under the False Claims Act was not addressed by the parties' motions or by this opinion. Presumably, if the infusion therapy was administered by a qualified non-physician practitioner, a proper claim could have been submitted and reimbursed at the lower rate for a physician's assistant, nurse practitioner, or clinical nurse specialist under 42 C.F.R. §§ 414.52 and 414.56, supra, if demonstrated to be compensable. Again, the present opinion does not address the level of payment available for physician's assistant services, if

The accompanying Order shall be entered.

January 6, 2010
Date

s/ Jerome B. Simandle
Jerome B. Simandle
U.S. District Judge

applicable.